

Remarks

Amendments

New claims 49-54 have been added. These claim specify monitoring of efficacy of the dose to improve language performance. Specific monitoring techniques include monitoring language fundamentals and problem solving. These claims are supported in the specification as originally filed. The last sentence of paragraph [21] teaches the use diagnostic tests to monitor efficacy: "Tests which are used diagnostically can also be used to monitor the efficacy of treatments." The end of paragraph [18] teaches the use of a problem solving test and a clinical evaluation of language fundamentals to diagnose: "Methods for diagnosing and measuring these conditions are known in the art. The Test of Problem Solving [Zachman et al., 1984] and the Clinical Evaluation of Language Fundamentals-Revised [Semel et al., 1986] can be used to objectively measure language performance. Other tests can be used as determined in the art." Thus the new claims add no new matter.

The Rejection of Claims 1-8, 10-12, and 16 Under 35 U.S.C. § 103(a)

Claims 1-8, 10-12, and 16 stand rejected over Pratt (US 6458807) or Ieni (US 2006/0018839 A1). This rejection is respectfully traversed.

The rejected claims are directed to prescribing for or treating individuals that have a specific learning disability. The specification defines a learning disability:

The most widely accepted definition of learning disability is provided by the Individuals with Disabilities Education Act (IDEA; Public Law 105 17) that is the basis for state and federal funding for children with special learning needs. PL 105 17 defines a specific learning disability as:

Those children who have a disorder in one or more of the basic psychological processes involved in understanding or in using language, spoken or written, which disorder may manifest itself in imperfect ability to listen, think speak, read, write, spell, or do mathematical calculations. Such disorders include such

conditions as perceptual handicaps, brain injury, minimal brain dysfunction, dyslexia, and developmental aphasia. Such term does not include children who have learning problems that are primarily the result of visual, hearing, or motor handicaps, of mental retardation, of emotional disturbance or environmental, cultural, or economic disadvantage.

Pratt is cited as teaching the use of donepezil to treat mild cognitive impairments. Pratt defines cognitive impairment as “an acquired deficit in one or more of memory function, problem solving, orientation and/or abstraction that impinges on an individual’s ability to function independently.” Col. 4, lines 41–45. Pratt defines mild cognitive impairments as “one or more minor symptoms of disorientation, impaired memory, impaired judgment, and/or impaired intellect.” Col. 5, lines 28–30.

Ieni is cited as teaching treatment of developmental delay. Paragraph [0023]. Developmental delay is defined by Ieni as “a child who fails to achieve certain skills as quickly as expected, i.e., a child not reaching developmental bench marks at the usual age. Signs of developmental delay can include the delay in walking and other motor skills, the inability to walk, language delay or inability to learn, abnormalities of vision or hearing, behavioral problems, and seizures.” Paragraph [0024].

It is respectfully submitted that neither Pratt nor Ieni teach treating the same population or teach the same effect as recited in the subject claims. Pratt is directed to treating an individual with an acquired condition, i.e., something acquired later in life due to a disease or medical event. Pratt defines the cognitive impairment that he treats as “an acquired deficit.” Acquired learning problems are not specific learning disabilities.

Ieni, like Pratt, teaches treatment for a variety of acquired conditions, such as the results of strokes. See paragraph [0026]. Specific learning disabilities, however, are not acquired. Ieni also teaches treating developmental delay. Developmental delay is also distinct from a learning disability.

It is respectfully submitted that both Pratt and Ieni teach treatment of different populations having different conditions than that claimed. Neither acquired conditions nor developmental delays are the same as learning disabilities.

Moreover, since neither Pratt nor Ieni teach that the recited cholinesterase inhibitors improve language information processing, one of skill in the art would not have been motivated to use these inhibitors on this population. Thus the methods of the present invention would not have been obvious over Pratt and Ieni, because they teach a different use of cholinesterase inhibitors.

The Office Action asserts that the use of cholinesterase inhibitors to treat cognitive impairments would render obvious the use to improve language information processing. But language information processing is just one of many, many cognitive functions. There was no reason to suspect from the cited prior art that cholinesterase inhibitors would improve language information processing.

As is clear from even a cursory knowledge of the art, brain function is at the moment a very unpredictable area. One of skill in the art could not make any hypotheses and have a reasonable expectation of success about brain function and the effect of drugs without rigorous testing. Even if, *arguendo*, one of skill in the art would have made a hypothesis to test the use of cholinesterase inhibitors for improving language function in individuals with specific learning disabilities, no reasonable expectation of success could have existed.

Withdrawal of this rejection is therefore respectfully requested.

The Rejection of Claims 23-40

Claims 23-40 are not specifically listed in the rejection on page 4, but they are discussed as if included in the rejection at page 7. Claims 23-40 are dependent claims which recite additional steps or characteristics of the subjects that relate directly to language processing or a specific learning disability. The Office Action concedes that neither of the two cited references teaches these additional steps or characteristics. However, it notes that one of skill in the art would “immediately recognize that these are treatments specifically designed for patients with cognitive disorders,” so it would have been obvious, the Office Action urges, to use these additional steps or characteristics to

improve the results with the drug. A reasonable expectation of success is further asserted.

As noted above, cognitive disorders, in particular as defined by Pratt, are different and do not include the specific learning disabilities as recited. Recall that Pratt defines cognitive impairment as “an acquired deficit in one or more of memory function, problem solving, orientation and/or abstraction that impinges on an individual’s ability to function independently.” Col. 4, lines 41-45. Pratt defines mild cognitive impairments as “one or more minor symptoms of disorientation, impaired memory, impaired judgment, and/or impaired intellect.” Col. 5, lines 28-30. These are not the specific learning disabilities of the present invention. Moreover, with regard to a reasonable expectation of success, there would have been no predictability that a drug allegedly good for one type of brain function would work for a different brain function. Brain functions are simply too unpredictable to make any such extrapolation with any reasonable expectation of success.

Nowhere do Pratt or Ieni suggest using reading or language therapy, for example. Nowhere do they suggest that such language areas would be improved. See claims 25-30, which recite reading and language therapies. Nowhere do Pratt or Ieni teach or suggest the verbal performance diagnosis recited in claims 39-40.

Moreover, with regard to new claims 49-54, nowhere do Pratt or Ieni teach or suggest the monitoring of human subjects to determine language performance. The effect on language processing that the present inventors have found was not taught or suggested in the prior art.

Respectfully submitted,

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